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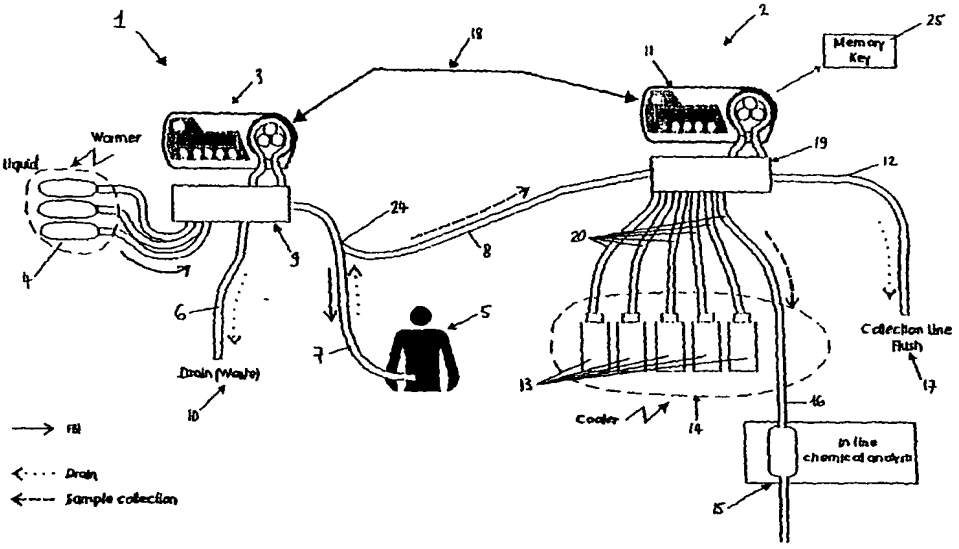
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PERITONEAL DIALYSIS SYSTEM



(57) Abstract: The invention relates to a peritoneal dialysis sampling system (2) to be used together with a peritoneal dialysis system (1) which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system (1) comprising a supplying line (7) and supplying means (3) for supplying dialysis fluid to the peritoneal cavity, a draining line (7) and draining means (3) for draining the fluid from the cavity, said peritoneal dialysis sampling system being characterized by the fact that it consists of an automatic sampling system (2) which is able to automatically sample volumic fractions of the dialysate contained in the peritoneum of the patient at specific time intervals in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

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Peritoneal dialysis system

The present invention relates to a peritoneal dialysis sampling system to be used in a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity.

Different tests have been proposed to evaluate the patient membrane characteristics in order to improve the exchanges of fluid during peritoneal dialysis according to each patient. For instance the PDC test according to Haraldsson and Rippe, based on the three pore model, is commonly used to achieve this objective. Other tests would also be of interest if they would be able to evaluate the specific outcome of a given peritoneal dialysis type of cycles for a given patient and be used to improve those cycles based on the peritoneal dialysis outcome.

However all present tests show some inconvenients and limitations. In particular they cannot be reliable enough due to the impossibility of carrying out measurements during certain periods such as dwell time. Those tests are also not able to directly evaluate the outcome of a given type of cycle but rather evaluate the membrane characteristics in order to calculate optimized cycles for the patient. With the PDC test for example, there must be a full exchange cycle before carrying the measurements on the drained volume. State of the art tests also not allow the automatic use of different liquids and/or different concentrations, nor the automatic sampling.
Furthermore they are particularly cumbersome for the patient since they have to be manually done over a 24h period of time, with typically 5 exchanges. Therefore, the use of those tests is today limited to certain patients and require specific conditions to be conducted.

One of the object of the present invention is to avoid the previous listed problems.

It relates to a peritoneal dialysis sampling system to be used in a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity, said peritoneal dialysis sampling system being characterized by the fact that it consists of an automatic sampling system which is able to automatically sample volumic fractions of the dialysate contained in the peritoneum of the patient at specific time intervals in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

The automatic sampling system is connected on the draining line either between the patient peritoneum and the draining means or between the draining means and a waste collector.

Connecting the automatic sampling system according to the invention on the draining line allows to carry out a test at any time by drawing liquid directly from the peritoneum. It also allows to take samples of fluid at different points of time and having different sample volumes during the same cycle. All these possibilities improve considerably the evaluation of the peritoneal membrane characteristics and/or the peritoneal dialysis outcome for a given patient.

In particular, the possibility to increase the number of sampling steps and automatically vary the dialysate volume and concentration over a certain period of time allows to increase the number of information collected over a limited period of time. As a result, a full and more detailed patient peritoneal membrane evaluation can be made over a shorter period of time, allowing such evaluation to be conducted automatically preferably overnight. In certain circumstances, it may be useful to add one or several more manual samplings over the day, although the more detailed information would have been collected over the night by use of the automatic sampling system according to the present invention.

Preferably the automatic peritoneal dialysis sampling system is provided with means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.

The evaluation of the peritoneal membrane characteristics may be improved by providing the automatic peritoneal dialysis sampling system with means, e.g. a system of valves and separate fluidic paths, in order to sample different peritoneal dialysis fractions and collect them in separate containers for a later detailed analysis of their specific content.

The automatic peritoneal dialysis sampling system may be connected between the patient peritoneum and the draining means, requiring sampling means to sample liquid from the peritoneum at different points of time. The sampling means may, for example, be of a peristaltic type allowing a precise volumic sampling. Alternatively, the sampling means may result from vacuum originating from the sampling containers which may be controlled by a series of valves, or by gravity. In another embodiment of the present invention the automatic peritoneal dialysis sampling system may be connected after the draining means, such draining means being used, in such case, for both draining the dialysis fluid after each cycle as well as collecting the sampling fractions. In the event of dwell time sampling, the draining means would be activated to sample the volumic fraction required during dwell time, while in the drain phase of each cycle only a fraction of the drainage volume would be collected by use, for example, of a valve system.

The connection of the automatic peritoneal dialysis sampling system to the draining line may also be made by an electromechanical valve which is actuated in relation with a specific functioning of the draining means.

When the connection of the automatic peritoneal dialysis sampling system to the draining line is situated between the patient peritoneum and the draining means, the automatic sampling can be made during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle without interfering with the peritoneal

dialysis system. When the connection of the automatic peritoneal dialysis sampling system is situated after the draining means, the automatic sampling can only occur during the drain phase of each cycle or, alternatively, can also occur during the dwell time provided the draining means are activated during such dwell time for that purpose. In the first case, the automatic peritoneal sampling system requires sampling means, while in the latest case the draining means of the peritoneal dialysis system are also used for sampling purposes.

The sampling means, if required, preferably include pumping means such as a peristaltic pump. They may also be of a gravity type, or vacuum type, if in connection with a series of valves.

In a preferred embodiment the automatic sampling system comprises a series of sampling containers, pumping means and a series of valves in order to direct a certain quantity of each fluid sample to a given sampling container.

The sampling containers may consist of soft pouches.

The automatic sampling system may be composed of a series of valves which are controlled by an electronic system in order to direct a certain quantity of each fluid sample to a specific sampling container. The valves may be of electromagnetic type.

Preferably the automatic sampling system comprises means for eliminating a volume of liquid between two samplings at least equivalent to the dead volume contained between the patient and the sampling level. This can be done by providing the system with a purging line. With such a configuration, after a first sampling, the draining line is connected to the purging line in order to purge the above cited dead volume in order to prevent mixing of two different samples. A second sampling occurs then when the draining line is connected to another sampling container. Purging can be obtained either by use of the sampling means or, in the configuration with draining means from the automatic peritoneal dialysis system, by use of such draining means.

Advantageously, both systems: the peritoneal dialysis system which comprises an automatic peritoneal dialysis exchange system, and the automatic peritoneal dialysis sampling system are connected to the patient peritoneum and comprise means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.

In a further embodiment, the automatic sampling system under the present invention can also be used to not only determine the membrane characteristics but also evaluate one or several peritoneal dialysis exchange cycles in order to determine the best appropriate exchange cycle or series of cycles for the patient.

In a preferred embodiment both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are similar systems which are synchronized and which are working with different software and fluidic connections. For instance, they both may comprise peristaltic pumps.

In another preferred embodiment of the present invention, the automatic peritoneal dialysis sampling system only consist of a series of electro-valves and containers, which electro-valves are controlled by the automatic peritoneal dialysis system. In such preferred embodiment, the sampling is directed from the peritoneum to the containers by use of the drawing means of the automatic peritoneal dialysis system which contains a specific order of sequence for the opening and closing of specific valves in connection with the peritoneal dialysis cycles.

The peritoneal dialysis system may comprise a memory key which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system according to the peritoneal dialysis cycles and to store the sampling information.

The automatic peritoneal dialysis sampling system may comprise means for sequentially collecting sample volumes in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

In order to store the samples in optimal conditions until analysis the sampling containers may preferably be enclosed inside a cooling box which comprises cooling means.

Advantageously the automatic peritoneal dialysis sampling system comprises analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means.

The automatic sampling system may be adapted to measure different constituents/parameters such as glucose, urea, creatinine, sodium, chloride, albumine, proteins, osmolarity or ph.

For instance the result of the in-line analysis is used to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation or directly evaluate the impact of specific changes on the peritoneal dialysis outcome for the patient.

Some embodiments of the invention will be discussed hereafter in a more detailed way.

Figure 1 illustrates a first embodiment of the system according to the invention where the automatic sampling system is connected on the draining line between the patient peritoneum and the draining means.

Figure 2 illustrates another embodiment of the system according to the invention where the automatic sampling system is connected on the draining line between the draining means and a waste collector.

The peritoneal dialysis system according to figure 1 consists of a first system 1 comprising a first peristaltic pump 3, dialysis fluid containers 4 , a line 6,7 consisting of a supplying/draining line 7 which is arranged between a patient 5 and the first peristaltic pump 3 and a draining line 6 which is arranged between the first peristaltic pump 3 and a first waste collector 10, the dialysis fluid containers 4 and the draining line 6 may be alternatively connected to the supplying/draining line 7 by a valve 9 e.g. of electromechanical type.
The supplying/draining line 7 is provided with a Y-site 24 in order to connect a sampling line 8.
The peritoneal dialysis system according to figure 1 also include an automatic sampling system 2 made of a second peristaltic pump 11, a collection line 12, sampling containers 13 linked to the sampling line 8 via conduits 20 and a analyzing line 16 comprising an analyzing unit 15. The sampling line 8, the conduits 20, the analyzing line 16 and the collection line 12 are all alternatively connected to the second peristaltic pump 11 by an appropriate valve 19.
The sampling containers 13 are arranged within a cooling container 14.
Both first system 1 and the automatic sampling system 2 may change information via a communication line 18 (by cable or by wireless communication). The automatic sampling system 2 is provided with a memory key 25 which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.

The automatic sampling system 2 can be programmed to take volumic fractions of liquid at predetermined times, for instance during the dwell time. Those volumic fractions may differ from each others.

The volumic fractions may also be taken during the drain cycle.
The collection line 12 allows to purge a dead volume between samplings.

Figure 2 shows another configuration, very similar to the configuration of figure 1, but which uses only one peristaltic pump 3 for supplying dialysis liquid to the patient, draining dialysis fluid from the patient and supplying volumic fractions to the automatic sampling system 2. In this configuration, the sampling line 8 is connected on the draining line 6. In said configuration, sampling are controlled by the peristaltic pump which may be activated for sampling purposes at any time, including during the dwell time.

Of course the invention is not limited to the above detailed embodiments. Generally it covers any automatic sampling system 2 which can take volumic fractions of liquid during a dwell cycle or a drain cycle.

Claims

1. A peritoneal dialysis sampling system to be used together with a peritoneal dialysis system which is programmed to deliver fluid to a peritoneal cavity of a patient and to drain the fluid from the cavity, said peritoneal dialysis system comprising a supplying line and supplying means for supplying dialysis fluid to the peritoneal cavity, a draining line and draining means for draining the fluid from the cavity, said peritoneal dialysis sampling system being characterized by the fact that it consists of an automatic sampling system which is able to automatically sample volumic fractions of the dialysate contained in the peritoneum of the patient at specific time intervals in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

2. Automatic peritoneal dialysis sampling system according to claim 1 furthermore comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences in order to better evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient..

3. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising means for allowing the use of different peritoneal dialysis liquids and/or different concentrations for each exchange cycle.

4. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising connecting means for allowing a connection to a Y-site on the draining which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system in order to collect samples at different intervals independently of the drain cycles.

5. Automatic peritoneal dialysis sampling system according to claim 4 furthermore comprising means for allowing the automatic sampling during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

6. Automatic peritoneal dialysis sampling system according to any of the claim 4 or 5 wherein it comprises a series of sampling containers, pumping means and a series of valves in order to direct a certain quantity of each fluid sample to a given sampling container.

7. Automatic peritoneal dialysis sampling system according to the previous claim wherein said pumping means is of a peristaltic type.

8. Automatic peritoneal dialysis sampling system according to any of the claims 1 to 3 furthermore comprising connecting means for connecting it to the draining line between the draining means and a waste collector in order to collect samples of specific drain cycles.

9. Automatic peritoneal dialysis sampling system according to claim 8 wherein the automatic peritoneal dialysis system is composed of a series of valves which are controlled by an electronic system in order to direct a certain quantity of each fluid sample to a specific sampling container.

10. Automatic peritoneal dialysis sampling system according to claim 9 wherein the valves of such automatic peritoneal dialysis sampling system are controlled by the automatic peritoneal dialysis system in order to open and close at specific time intervals in relation with the peritoneal dialysis cycles.

11. Automatic peritoneal dialysis sampling system according to any of the claims 6 or 9, wherein the valves are of an electromagnetic type.

12. Automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising means for eliminating a volume of liquid between two samplings at least equivalent to the dead volume contained between the patient and the sampling level.

13. Peritoneal dialysis system including an automatic peritoneal dialysis sampling system according to any of the previous claims furthermore comprising an automatic peritoneal dialysis exchange system, both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system being connected to the patient peritoneum and comprising means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.

14. Peritoneal dialysis sampling system according to the previous claim wherein both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are similar systems which are synchronized and which are working with different software and fluidic connections.

15. Automatic peritoneal dialysis sampling system according to any of the previous claims wherein it comprises a memory key which contains all the necessary data to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.

16. Automatic peritoneal dialysis sampling system according to any of the previous claims wherein sampling containers consist of soft pouches.

17. Automatic peritoneal dialysis sampling system according to any of the previous claims 1 to 15, wherein sampling containers consist of containers with vacuum in order to draw the liquid automatically when in open connection with the drawing line.

18. Automatic peritoneal dialysis sampling system according to any of the claims 1 to 15, furthermore comprising means for sequentially collecting sample volumes in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

19. Automatic peritoneal dialysis sampling system according to any of the previous claims 6 to 18 wherein said sampling containers are enclosed inside a cooling box which comprises cooling means to maintain the samples in optimal condition for storage until analysis.

20. Automatic peritoneal dialysis sampling system according to any of the previous claims wherein it comprises analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means.

21. Automatic peritoneal dialysis sampling system according to the previous claim wherein said analyzing means allow the measurement of at least one of the following constituents or characteristics : glucose, urea, creatinine, Sodium, Chloride, albumine, proteins, osmolarity or ph.

22. Method of use of the automatic peritoneal dialysis sampling system according to any of the previous claims 20 or 21 wherein the result of the in-line analysis is used to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a given patient.

23. Method of use of the automatic peritoneal dialysis sampling system according to any of the previous claims wherein the specific time intervals for sampling volumic fractions are defined in relation with the peritoneal dialysis program sequences in order to better evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

24. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 22 wherein different peritoneal dialysis liquids and/or different concentrations are used for each exchange cycle, whether it is a tidal exchange or a full exchange cycle.

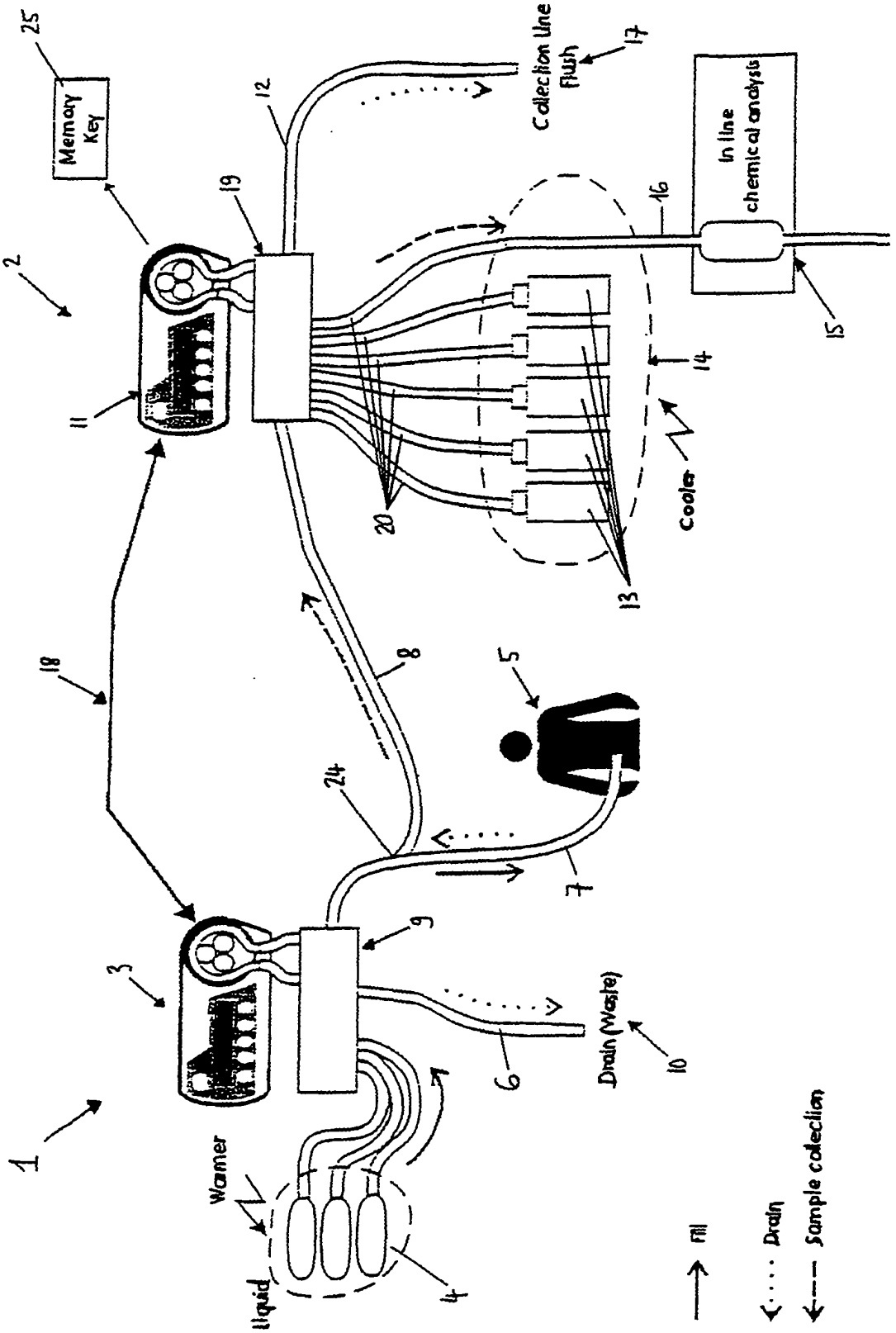
25. Method of use of the automatic peritoneal dialysis system according to any of the previous claims, wherein the automatic sampling occurs during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient.

26. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 21 wherein a volume of liquid at least equivalent to the dead volume contained between the patient and the sampling level is eliminated between two samplings .

27. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 15 and 18 to 21, wherein the sampling volumes are sequentially collected in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

28. Method of use of the automatic peritoneal dialysis system according to any of the claims 1 to 21 wherein the samples are directly analyzed in-line, such as by spectrometric, fluorometric, electro-chemical or chemical means.

29. Method of use according to the previous claim wherein the result of the in-line analysis is used to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a given patient.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19
16
2
11
15
14
20
Cooler
13
18
8
5
24
7
9
3
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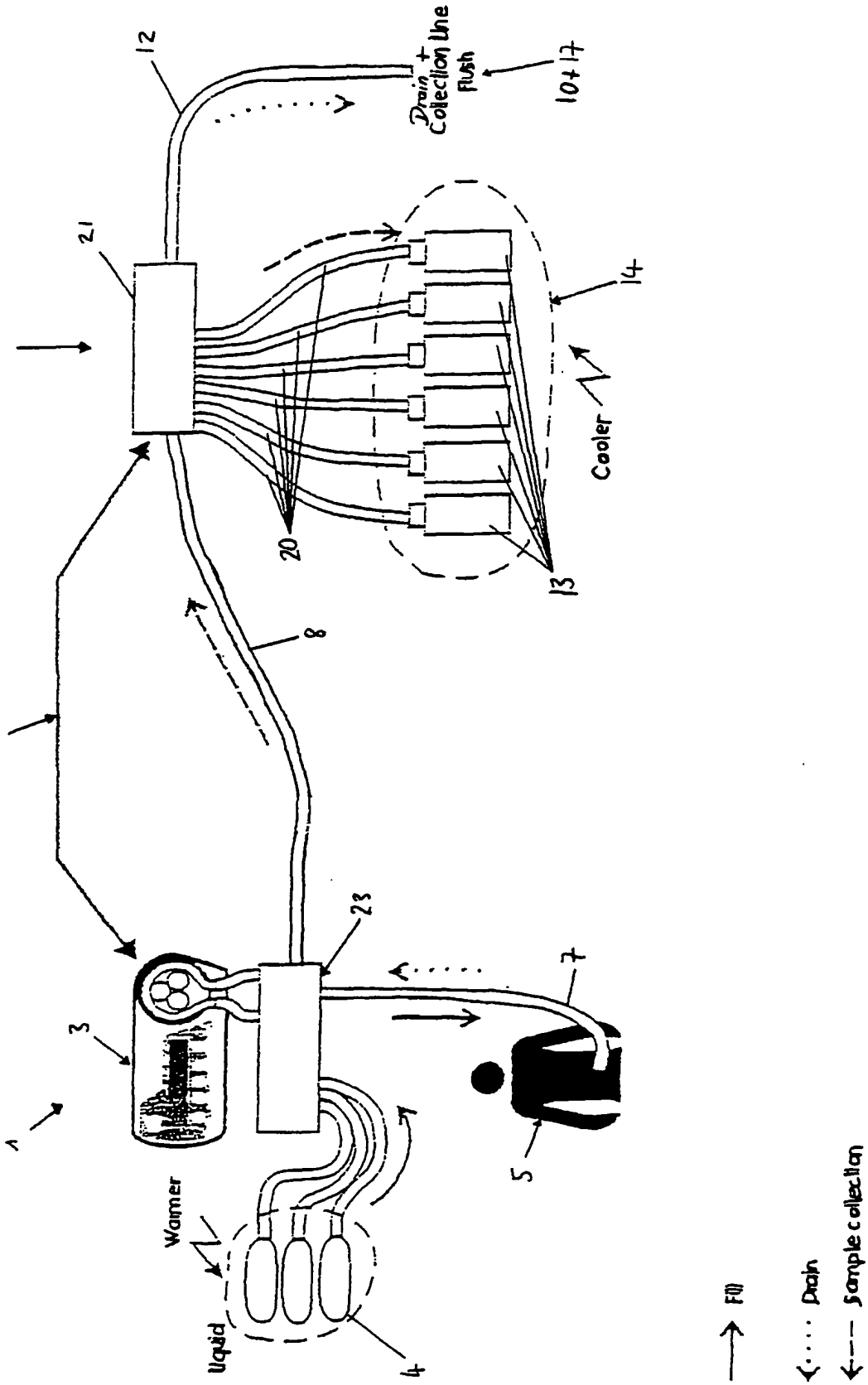
10
6
1
Warmer
Liquid
4
Fill
Drain
Sample collection

FIG. 1

FIG. 2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2
14
Cooler
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13
8
22
23
7
3
1
Warmer
Liquid
4
5
Fill
Drain
Sample collection

INTERNATIONAL SEARCH REPORT

International Application No
PCT/[redacted]03/00048

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 06082 A (DADSON JOSEPH E) 11 February 1999 (1999-02-11) page 6, line 19 -page 16, line 7; figure 9 page 19, line 16 -page 20, line 5	1-5, 8-13, 15-17, 20,21
X	DE 100 49 900 C (FRESENIUS MEDICAL CARE DE GMBH) 25 October 2001 (2001-10-25) & US 2002/107474 A1 (NOACK JOACHIM) 8 August 2002 (2002-08-08) page 2, left-hand column, line 48 -page 3, right-hand column, line 20	1,2,4-7, 12-15, 20,21
X	US 4 618 343 A (POLASCHEGG HANS-DIETRICH) 21 October 1986 (1986-10-21) column 8, line 9 -column 10, line 32	1,2,4-7, 20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2003	20/05/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Kroeders, M

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH 03/00048

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 22-29
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter[illegible]nal Application No
PCT/C[illegible]8/00048

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